

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK



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Accredited to
ISO 15189:2012

Birmingham Women's and Children's Hospital NHS Foundation Trust

Issue No: 003 Issue date: 08 December 2020

Blood Sciences Department
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Testing performed at the above address only

Site activities performed away from the locations listed above:

Location details	Activity
<p>Emergency Department Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p> <p>Contact: Mr Richard Cole, Section Head, Blood Transfusion. Tel: 0121 333 9858. Email: richardcole1@nhs.net</p>	Blood storage & issue only
<p>Ward 15 Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	Blood storage & issue only
<p>Theatre 8 Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	Blood storage & issue only
<p>Theatre 7 Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	Blood storage & issue only
<p>Theatre 4 Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	Plasma freezer, storage & issue only
<p>PICU Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	Blood storage & issue only
<p>Histology store Birmingham Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	Plasma freezer



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS:	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Plasma/Whole blood	<p>Blood Group by detection and identification of antigens:</p> <p>ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative</p> <p>Neonatal Blood Group (ABO and RhD) and Direct Antiglobulin Test DAT :</p> <p>ORhD positive ORhD negative ARhD positive A RhD negative B RhD positive B RhD negative AB RhD positive AB RhD negative</p>	<p>Manual Rapid Provisional Group ABO and Rh D using Bioscot Monoclonal reagents (Lorne Laboratories): Anti-A (BIRMA-1), Anti-B (LB-2), Anti-D (MS-201), Anti-D (RUM-1) SOP: Rapid Provisional Group HSB0433</p> <p>2nd person manual check group: ABO and Rh D using Bioscot Monoclonal reagents (Lorne Laboratories): Anti-A (BIRMA-1), Anti-B (LB-2) and Anti-D (MS-201) SOP: Rapid spin Group (Check Group) HSB0027</p> <p>Automated Diamed ID-Card, DiaClon ABO/D+Reverse Group: Monoclonal Anti-A, Anti-B, Anti-D(VI-), Control; Diamed ID-DiaCell A1 cells and B cells. (Diamed Gel Station Blood Group Analyser) SOP: ABO and Rhesus Full Group HSB0026</p> <p>Automated Diamed ID-DiaClon ABO/RhD Newborn: Monoclonal Anti- ; Anti-B ; Anti-A,B ; Anti D(VI) ; Control ; Polyspecific DAT (Anti IgG+C3d).</p> <p>Manual Diamed ID-DiaClon ABO/RhD Newborn: Monoclonal Anti- ; Anti-B ; Anti-A,B ; Anti D(VI) ; Control ; Polyspecific DAT (Anti IgG+C3d). SOP : Neonatal Group and DAT HSBNDG0355</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations (cont'd):</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood	<p>Screening and identification of antibodies to :</p> <p>Rh (C, D, E, c, e, Cw) Kell (K, k, Kpa, Kpb, Jsa, Jsb) Duffy (Fya, Fyb) Kidd (Jka, Jkb) Lewis (Lea, Leb) P1 MNS (M, N, S, s) Lutheran (Lua, Lub) and Xga</p> <p>Compatibility Testing of patients plasma with donor cells</p> <p>Direct Antiglobulin Test</p> <p>Antigen phenotyping: Rh and Kell Phenotype C, D, E, c, e, Kell (K)</p> <p>M Phenotype:</p>	<p>Diamed ID-Card LISS/Coombs (IgG+C3d); Dia-Cell 1-11-111 Screening Cells and Diamed ID-DiaPanel</p> <p>SOP : Antibody Screening and Identification HSB392</p> <p>Diamed ID-Card LISS/Coombs (IgG+C3d)</p> <p>SOP: Compatibility Test (Crossmatch) HSB0395</p> <p>Diamed ID-Card LISS/Coombs (IgG+C3d) and monospecific using Diamed ID-Card DC Screening II (IgG and C3d)</p> <p>SOP: Direct Antiglobulin Test HSB0193</p> <p>Manual methods using Diamed Gel Card:</p> <p>SOP: Rh and Kell Phenotyping HSB0468</p> <p>M antigen phenotyping (Diamed Gel Card)</p> <p>SOP : M Antigen Phenotyping HSB0472</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood	<p>Full Blood Count: Haemoglobin platelet count red blood cell count mean cell volume haematocrit mean cell haemoglobin mean cell haemoglobin concentration white blood cell count white blood cell differential</p> <p>Reticulocyte count</p> <p>Nucleated red cell count</p>	<p>Sysmex XN2000 FBC analyser. Method - Fluorescence flow cytometry method, hydrodynamic focussing DC detection, SLS haemoglobin method</p> <p>SOP - FBC Validation (BSAH/PS/16)</p> <p>Sysmex XN2000 FBC analyser. Method - Fluorescence flow cytometry method. SOP - FBC Validation (BSAH/PS/16)</p> <p>Sysmex XN2000 FBC analyser. Method - Fluorescence flow cytometry method. SOP - FBC Validation (BSAH/PS/16)</p>
Peripheral blood	Microscopic analysis of blood films to determine morphological abnormalities	<p>Hematek stain machine, microscope. Method – Staining (modified Wright's stain), microscopic examination.</p> <p>SOP - Performing a manual differential using the Extended-Intelligent Processing Unit (EPU) (BSAH/PS/13)</p> <p>SOP - Blood and Bone Marrow Film Preparation (HSR0287)</p> <p>SOP - Microscopic film examination (HSR0023)</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations (cont'd):</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood	Malaria screening for: Plasmodium Falciparum and / or other species (P. Ovale, P. Malariae, P. Vivax, P. Knowlesi).	Commercial kit - Carestart malaria rapydtest. Method - Immunoassay. SOP - CareStart Malaria RDT (HSR0467)
	Detection & speciation (thin films) of malaria parasites: Plasmodium Falciparum, P. Ovale P. Malariae P. Vivax P. Knowlesi.	Manual staining: SOP - Giemsa Stain pH 7.2 (HSR0360)
	Glucose 6 Phosphate Dehydrogenase screen	Commercial kit - Trinity Biotech G6PD Deficiency, Longwave UV light source. Method - Visual fluorescence screening. SOP - G6PD Screen (HSR0293)
Whole blood, Plasma (citrate or EDTA), Serum.	Detection of infectious mononucleosis heterophile antibodies	Commercial kit - Clearview® IM II Test for Infectious Mononucleosis. Method - Immunoassay. SOP - Clearview® IM II Test for Infectious Mononucleosis (BS/PS/17)
Whole Blood	Erythrocyte Sedimentation Rate (ESR)	Commercial kit - Sarstedt Microvette CB200. Manual method - Sedimentation. SOP - ESR Examination - Sarstedt method (BSAH/PS/17)



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations (cont'd):</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Whole Blood	Haemoglobinopathy analysis by detection of haemoglobin variants: Hb S detection	Commercial kit - Microgen Bioproducts S-Test SOP - Sickle Solubility Test (HSR0357)
Blood	Detection of: α and β thalassaemia abnormal haemoglobins e.g. HbC / D / E / S. Determination of HbF and HbS levels.	Biorad D10 HPLC analyser. Method - High Performance Liquid Chromatography. SOP - Biorad D10 HPLC screen (HSR0463)
Serum	Haptoglobin	Commercial kit - Siemens Nor-Partigen Haptoglobin plate. Method - Radial immunodiffusion. SOP - Serum Haptoglobin (HSR0351)
Citrated Plasma	<u>Special Coagulation examinations to assist in clinical investigations</u> Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Clauss Fibrinogen (Fbg) Thrombin Time / Protamine Sulphate Time (TT/TTPS) International Normalised Ratio (INR) Anti-Xa Assays (LMWH and UFH) (Chromogenic assay)	Sysmex CS2000i Analyser - using Manufacturer's Reagent SOP: HSC0484 SOP: SOP HSC0486 SOP HSC0491 SOP HSC0487 SOP HSC0485 SOP HSC0492



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HUMAN BODY FLUIDS (cont'd)	<u>Special Coagulation examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Citrated Plasma		Sysmex CS2000i Analyser - using Manufacturer's Reagent
	Screening Test for Neutralising Factor Inhibitors (II, V, VII, VIII, IX, X, XI, XII, VWF)	SOP HSC0488
	Bethesda Assay for VIII Neutralising Inhibitors	SOP HSC0500
	Factor II Assay (One-Stage) (PT based clotting)	SOP HSC0505
	Factor V Assay (One-Stage) (PT based clotting)	SOP HSC0506
	Factor VII Assay (One-Stage) (PT based clotting)	SOP HSC0507
	Factor VIII Assay (One-Stage) (APTT based clotting)	SOP HSC0494
	Factor VIII Assay (Chromogenic)	SOP HSC0501
	Factor VIII Assay - Refacto AF (One-Stage) (APTT based clotting)	SOP HSC0502
	Factor IX Assay (One-Stage) (APTT based clotting)	SOP HSC0495
	Factor X Assay (One-Stage) (PT based clotting)	SOP HSC0508
	Factor XI Assay (One-Stage) (APTT based clotting)	SOP HSC0496
Factor XII Assay (One-Stage) (APTT based clotting)	SOP HSC0497	
Factor XIII Assay (chromogenic)	SOP HSC0509	



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HUMAN BODY FLUIDS (cont'd)	<u>Special Coagulation examinations to assist in clinical investigations (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Citrated Plasma	Von Willebrand Factor (vWF) Antigen Assay	SOP HSC0490
	Von Willebrand Factor (vWF) Activity Assay	SOP HSC0511
	Antithrombin Activity Assay (AT)	SOP HSC0499
	Protein S (Free) Antigen Assay	SOP BSSH001
	Protein C Activity Assay	SOP HSC0498
	Lupus Anticoagulant Screen (dRVVT)	SOP HSC0315
Peripheral Blood	Peripheral Blood Stem Cell Assay CD34	Beckman Coulter Navios Flowcytometer: SOP: BSSH/PS/7
	Lymphocyte Subsets (Immune Monitoring) CD3, CD4, CD8, CD19, CD16/56	SOP: BSSH/PS/8
	EMA for Hereditary Spherocytosis	SOP: BSSH/PS/5
	Platelet Glycoprotein Assay CD41, CD42b, CD61, CD62p	SOP: BSSH/PS/9



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Plasma	3-Hydroxy Butyrate	Roche Cobas 501 – enzymatic method– 3 rd party (Randox) SOP I/S/H/025
Plasma/Serum	Alanine Amino Transferase	Roche Cobas 501 – enzymatic method – Roche reagent SOP S/S/A/062
Plasma/Serum	Albumin	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/A/064
Plasma/Serum	Alkaline Phosphatase	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/A/065
Plasma	Ammonia	Roche Cobas 501 – enzymatic method– 3 rd party (Randox) SOP S/S/A/095
Plasma/Serum, Urine, Fluid	Amylase	Roche Cobas 501 – enzymatic colorimetric method – Roche reagent SOP S/S/A/066
Plasma/Serum	Aspartate Transaminase	Roche Cobas 501 – enzymatic method – Roche reagent SOP S/S/A/063
Plasma/Serum	Bilirubin -Total	Roche Cobas 501 – colorimetric diazomethod – Roche reagent SOP S/S/B/102



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examinations to assist in clinical investigations (cont'd)</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Plasma/Serum, Urine	Bilirubin - Direct	Roche Cobas 501 – colorimetric method – 3 rd party(WAKO) reagent SOP S/S/B/112.
Plasma/Serum, Urine	Bicarbonate	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/B/067
Plasma/Serum	C-reactive Protein	Roche Cobas 501 – particle enhanced immunoturbidimetric method – Roche reagent SOP S/S/C/073
Plasma/Serum, Urine Fluid	Calcium	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/C/068
Plasma/Serum, Urine Fluid	Creatinine	Roche Cobas 501 – enzymatic method – Roche reagent SOP S/S/C/075
Plasma/Serum	Cholesterol	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/C/072
Plasma/Serum, Urine Fluid	Chloride	Roche Cobas 501 – indirect ISE– Roche reagent SOP S/S/C/069
Plasma/Serum	Creatine Kinase	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/C/074
Plasma/Serum	Free Fatty Acids	Roche Cobas 501 – colorimetric method– 3 rd party (Randox) SOP I/S/F/029



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Plasma/Serum	Gamma-Glutamyl transferase	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/G/076
Plasma/Serum, Urine	Glucose	Roche Cobas 501 – enzymatic reference method with hexokinase– Roche reagent SOP S/S/G/086
Plasma/Serum, Urine	High Density Lipoprotein Cholesterol	Roche Cobas 501 – Homogenous enzymatic colorimetric method– Roche reagent SOP S/S/H/108
Plasma/Serum	Immunoglobulins IgA, IgM, IgG	Roche Cobas 501: Roche Cobas 501 – immunoturbidometric method – Roche reagent SOP S/S/I/104
Plasma/Serum	Iron	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/I/107
Plasma/Serum	Lactate Dehydrogenase	Roche Cobas 501 - Optimized standard method according to the Deutsche Gesellschaft für Klinische Chemie (DGKC). Roche reagent SOP S/S/L/096
Plasma/Serum / CSF	Lactate	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/L/082
Serum/Plasma	Magnesium	Roche Cobas 501 – colorimetric endpoint method – Roche reagent SOP S/S/M/098



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Serum	Methotrexate	Roche Cobas 501 – Homogenous enzyme immunoassay method– 3 rd party (ARK reagent) SOP BSAC/PS/1
Plasma/Serum	Paracetamol	Roche Cobas 501 – Homogenous enzyme immunoassay method Roche reagent SOP S/S/P/099
Plasma/ Serum / Urine / Fluid / Faeces	Potassium	Roche Cobas 501 – indirect ISE– Roche reagent BS/SOP/676
Plasma /Serum / Urine	Phosphate	Roche Cobas 501 – Molybdate UV photometric– Roche reagent SOP S/S/P/101
Plasma /Serum / Urine/ Fluid	Total Protein	Roche Cobas 501 – colorimetric method – Roche reagent SOP S/S/T/079
CSF	CSF Protein	Roche Cobas 501 – turbidimetric method – Roche reagent SOP S/S/P/007
Plasma /Serum / Urine / Fluid / Faeces	Sodium	Roche Cobas 501 – indirect ISE– Roche reagent SOP S/S/S/070
Plasma/Serum	Salicylate	Roche Cobas 501 – photometric method – Roche reagent SOP S/S/S/100
Plasma/ Serum / Fluid	Triglyceride	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/T/106



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Plasma/Serum / Urine / Fluid	Urea	Roche Cobas 501 – kinetic photometric method – Roche reagent SOP S/S/U/103
Plasma/Serum	Uric Acid	Roche Cobas 501 – enzymatic colorimetric method– Roche reagent SOP S/S/U/078
Plasma/Serum	Unbound Iron binding capacity	Roche Cobas 501 –colorimetric method– Roche reagent SOP S/S/U/093
Plasma/Serum	Alpha-Fetoprotein	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/A/094
Serum	Ferritin	Roche Cobas 601 – sandwich chemiluminescent immunoassay – Roche reagent SOP S/S/116 Ferritin
Plasma/Serum	Free Thyroxine	Roche Cobas 601 –competitive chemiluminescent immunoassay– Roche reagent SOP S/S/F/084
Serum	Oestradiol	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent. SOP BS/SOP/702
Plasma/Serum	Free Tri-iodothyronine (FT3)	Roche Cobas 601 –competitive chemiluminescent immunoassay– Roche reagent SOP BSAC/PS/37
Serum	Folate	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent SOP S/S/115 Folate



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Plasma/Serum	Follicle Stimulating Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/F/089
Plasma/Serum	Growth Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/G/097
Plasma/Serum	Luteinising Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/L/091
Serum	Parathyroid Hormone	Roche Cobas 601 –sandwich chemiluminescent immunoassay– Roche reagent SOP S/S/P/099
Plasma/Serum	Cortisol	Roche Cobas 601 –competitive chemiluminescent immunoassay– Roche reagent SOP S/S/C/088
Serum	Vitamin B12	Roche Cobas 601 – competitive chemiluminescent immunoassay – Roche reagent SOP S/S/114 Vitamin B12
Blood	Glycated Haemoglobin A1c (HbA1c)	Roche Cobas 501 turbidimetric inhibition immunoassay – Roche Reagent SOP S/S/H/025
Urine	Microalbumin	Roche Cobas 501 immunoturbidimetric– Roche Reagent SOP S/S/M/087



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Sweat	Chloride -Sweat	Collection -pilocarpine iontophoresis using Webster sweat inducer Collected via Wescor macroduct sweat collection system SOP BSAC/PS/21
Sweat	Sweat Conductivity	Analysis Sherwood 926S Chloride Analyser MK II via Coulometric titration BSAC/PS/10
Plasma/ Serum / Urine	Osmolality	Westcor sweat check conductivity meter conductivity BSAC/PS/10
Faeces	Detection of occult blood	Vitech 3320 Freezing Point Osmometer: SOP S/S/O/033
		Hema screen – guaiac peroxidase colour change BSAC/PS/11
END		